IS 12227 (2002): Sterile Single-Use Syringes, With or Without Needle, for Insulin [MHD 12: Hospital Equipment]

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IS 12227 : 2002
ISO 8537 : 1991
(Reaffirmed - 2012)

भारतीय मानक

इन्सुलिन के लिए सुई सहित अथवा सुई रहित निर्जीवाणुकृत एक बार उपयोग की जाने वाली सिरिंजें

(पहला पुनरीक्षण)

Indian Standard

STERILE SINGLE-USE SYRINGES, WITH OR WITHOUT NEEDLE, FOR INSULIN

(First Revision)

ICS 11.040.20

BUREAU OF INDIAN STANDARDS
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NEW DELHI 110002

June 2002

Price Group 9

NATIONAL FOREWORD

This Indian Standard (First Revision) which is identical with ISO 8537 : 1991 'Sterile single-use syringes, with or without needle, for insulin' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendations of Medical Instruments and Disposables Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1987. Its first revision has been undertaken with a view to align its requirements with the corresponding ISO 8537 brought out in 1991 and adopt it as a dual number standard.

Amendment No. 1 to ISO 8537 brought out in 2000 is reproduced at the end of the text of this standard.

This standard deals with products primarily intended for use with humans and provides performance requirements, but permits some variations of design and of the methods of packaging and sterilization by individual manufacturers.

Materials to be used for the construction and lubrication of sterile syringes and needles for single-use are not specified as their selection will depend to some extent upon the design, process of manufacture and sterilization method employed by individual manufacturers.

Syringes and needles should be manufactured and sterilized in accordance with recognized national or international codes of good manufacturing practice for medical devices, and should be free from defects affecting appearance, safety and serviceability of their intended use.

Certain grades of polypropylene, polystyrene and styrene/acrylonitrile copolymer have been extensively used for the barrels of sterile syringes for single-use. A high quality natural rubber composition is frequently used for the piston, although other materials such as silicone rubber are also used, the surface of the piston being lubricated with polydimethylsiloxane. For 2 ml syringes, high density polyethylene is frequently used for the seal of the two-component design of syringe in combination with a polypropylene barrel containing a fatty acid amide slip additive.

When selecting materials, the following should be considered:

a) Materials used in the construction of the wall of the syringe barrel should be of sufficient clarity to enable dosages to be read without difficulty and for air bubbles to be seen.

b) The materials of syringes and needles (including lubricant) and packaging should not, in their final form after sterilization and under conditions of normal use, detrimentally affect the efficacy, safety and acceptability of insulin preparations: neither should the construction materials be themselves affected physically or chemically by insulin preparations.

c) The materials should not cause the syringes and needles to yield, under conditions of normal use, significant amounts of toxic substances and should permit them to satisfy the appropriate national requirements or regulations for freedom from pyrogenic materials and abnormal toxicity. For testing these properties, an extract as specified in Annex H may be used.

It is strongly recommended that regulatory authorities, pharmacopoeiae and relevant trade associations should recognize the need for further testing, especially for incompatibility between the insulins and syringes when they are in contact for prolonged periods.

Where Indian Pharmacopoeia or other government regulations are legally binding, these requirements may take precedence over this Indian Standard.

(*Continued on third cover*)

AMENDMENT 1

Page 1

Clause 2 Normative references

Add "ISO 9626, *Stainless steel needle tubing for manufacture of medical devices*".

Definition 3.1

Change "gratuated" to "graduated".

Page 5

Clause 13 Needles

Change the title to "**Needle tubing and needles**". Delete the entire text, and substitute the following new text.

13.1 Needles for syringes of types 3 and 4

Needles for syringes of types 3 and 4 shall be in accordance with ISO 7864, except for the dimensions and test parameters which shall be in accordance with annex D of this International Standard.

13.2 Needle tubing for syringes of types 5, 6, 7 and 8

Needle tubing for syringes of types 5, 6, 7 and 8 shall be in accordance with ISO 9626, except for the dimensions and test parameters which shall be in accordance with annex D of this International Standard. The needle point shall be in accordance with ISO 7864.

NOTE ISO 9626:1991 is at present undergoing amendment; the values in annex D (see below) are taken from the most recent draft. Some values therefore differ from those given in ISO 7864:1993 and ISO 9626:1991. When the ISO 9626 amendment is published, clause 13 and annex D of this International Standard may be replaced by a normative cross-reference to ISO 7864 and amended ISO 9626.

Page 12

Annex D

Delete the entire annex D and substitute the following.

Annex D
(normative)

Properties of needles and needle tubing

D.1 The diameters of the needle tubing shall be in accordance with Table D.1.

Table D.1 — Diameters of needle tubing

Dimensions in millimetres

Nominal outside diameter [a]	Outside diameter		Minimum inside diameter
	min.	max.	
0,25	0,254	0,267	0,114
0,30	0,298	0,320	0,133
0,33	0,324	0,351	0,133
0,36	0,349	0,370	0,133
0,40	0,400	0,420	0,184
0,45	0,440	0,470	0,232

[a] The nominal outside diameters correspond to gauge numbers as follows: 0,25 mm (gauge 31), 0,30 mm (gauge 30), 0,33 mm (gauge 29), 0,36 mm (gauge 28), 0,40 mm (gauge 27) and 0,45 mm (gauge 26).

D.2 The stiffness of the needle tubing shall be in accordance with Table D.2 when tested as described in ISO 9626.

Table D.2 — Stiffness

Nominal outside diameter	Span mm ± 0,1	Force N ± 0,1	Maximum deflection mm
0,25	3,5	5,5	0,35
0,30	5,0	5,5	0,40
0,33	5,0	5,5	0,32
0,36	5,0	5,5	0,25
0,40	9,5	5,5	0,60
0,45	10,0	6,0	0,56

D.3 The minimum strength of the bond between the hub/syringe and the needle tubing shall be 22 N when tested in accordance with ISO 7864.

D.4 The stylet diameter to test the patency of the lumen as described in ISO 7864 shall be in accordance with Table D.3.

Table D.3 — Size of stylet to test patency of lumen

Dimensions in millimetres

Nominal outside diameter	Diameter of stylet $^{0}_{-0,01}$
0,25	0,08
0,30	0,11
0,33	0,11
0,36	0,11
0,40	0,15
0,45	0,18

D.5 The resistance to breakage shall be assessed in accordance with Table D.4 when tested as described in ISO 9626.

Table D.4 — Resistance to breakage

Dimensions in millimetres

Nominal outside diameter	Distance between rigid supports and application of bending force ± 0,1
0,25	8
0,30	8
0,33	8
0,36	8
0,40	8
0,45	10

(*Continued from second cover*)

This standard describes syringes with or without needles for use with 40 units of insulin/ml (U-40) and 100 units of insulin/ml (U-100). It is recommended that syringes graduated for only one strength of insulin be used to avoid accidents. For using more than one strength of insulin, the importance of having individual syringes appropriately graduated for only one strength of insulin as specified in this standard is emphasized. Serious problems may result if a syringe is used with a strength of insulin for which it is not designed. If the syringe is used for mixing different types of insulin, it is strongly recommended that the procedure is performed in the same order each time.

Annexes A, B, C, D, E, F and G form an integral part of this standard. Annexes H and J are for information only.

The text of standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'; and

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their place are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 594-1 : 1986	IS 3234 (Part 1) : 1986 Conical fittings with a 6 percent (Luer) taper for syringes, needles and other medical equipment: Part 1 General requirements (*second revision*)	Identical
ISO 7864 : 1993	IS 10654 : 2002 Sterile hypodermic needles for single use (*third revision*)	do

The technical committee responsible for the preparation of this standard has reviewed the provisions of ISO 9626, referred in this adopted standard and has decided that it is acceptable for use in conjunction with this standard.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

IS 12227 : 2002
ISO 8537 : 1991

Indian Standard

STERILE SINGLE-USE SYRINGES, WITH OR WITHOUT NEEDLE, FOR INSULIN
(First Revision)

1 Scope

This International Standard specifies requirements and test methods for sterile syringes with or without needles intended for single use solely for the injection of insulin and primarily in humans It covers syringes for use with 40 units of insulin/ml (U-40) and 100 units of insulin/ml (U-100)

Sterile syringes specified in this International Standard are intended for use soon after filling as they are not suitable for containing insulin over extended periods of time

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard At the time of publication, the editions indicated were valid All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below Members of IEC and ISO maintain registers of currently valid International Standards

ISO 594-1 1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1 General requirements*

ISO 7864 1988, *Sterile hypodermic needles for single use*

3 Definitions and nomenclature

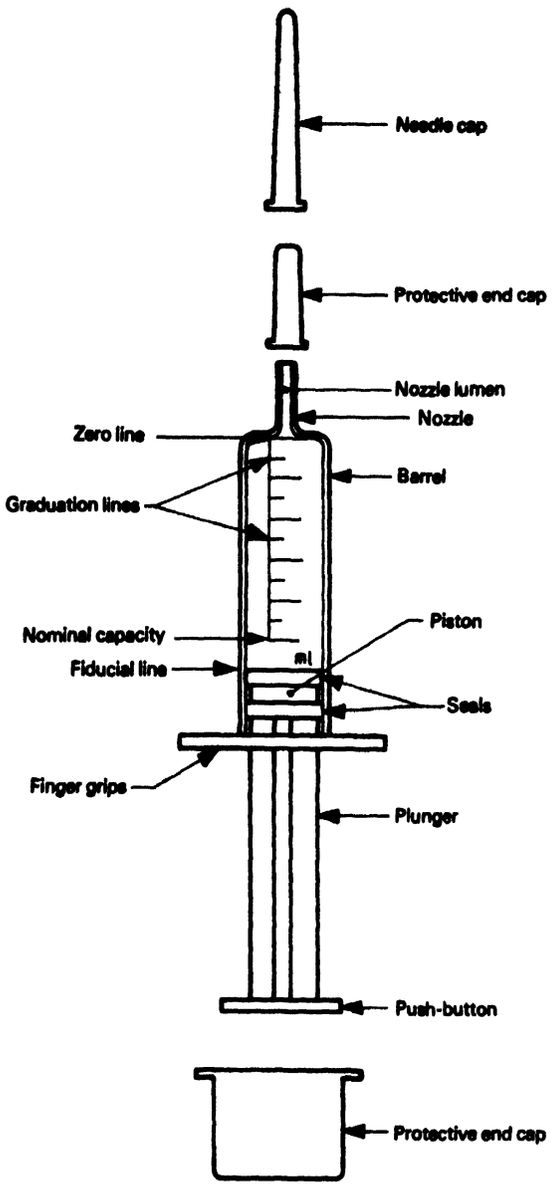
For the purposes of this International Standard, the following definitions apply The nomenclature of some components of syringes for single use is given in figure 1

3.1 **gratuated capacity:** Volume of water at 20 °C ± 3 °C or 27 °C ± 3 °C expelled from the syringe when the fiducial line on the piston traverses a given scale interval or intervals

3.2 **needle cap:** Protective end cap intended to maintain the sterility of the needle tube and to protect physically the needle tube and needle hub, if present

3.3 **needle sheath:** Cover intended to provide physical protection to the needle tube

3.4 **protective end caps:** Covers intended to enclose the projecting portion of the plunger and push-button at one end and the nozzle and/or the needle at the other end



NOTE — The drawing is intended to be illustrative of components of a syringe only. It does not show a detachable needle or a permanently attached needle tube, and does not form part of the specification. The piston/plunger assembly may or may not be of integral construction and may incorporate more than one seal.

Figure 1 — Schematic representation of insulin syringe for single use

4 Types of syringe

The types of syringe shall be designated as follows in relation to their packaging and combinations with needles:

Type 1: Syringe having a 6 % (Luer) male conical fitting, supplied without a needle and packaged in a unit container.

Type 2: Syringe having a 6 % (Luer) male conical fitting, and supplied without a needle and fitted with protective end caps.

Type 3: Syringe having a 6 % (Luer) male conical fitting, and supplied with a detached or detachable needle and packaged in a unit container.

Type 4: Syringe having a 6 % (Luer) male conical fitting, and supplied with a detachable needle and fitted with protective end caps.

Type 5: Syringe having a fitting other than a 6 % (Luer) taper, supplied with a needle not intended to be detached and packaged in a unit container.

Type 6: Syringe having a fitting other than a 6 % (Luer) taper, supplied with a needle not intended to be detached and fitted with protective end caps.

Type 7: Syringe with fixed needle tube and packaged in a unit container.

Type 8: Syringe with fixed needle tube and fitted with protective end caps.

NOTE 1 Eight types are designated to encompass different presentations, but it is likely that the number of types in use in a particular country will be less than eight.

5 Freedom from extraneous matter

The surfaces of the syringe and needle which come in contact with insulin shall be clean and free from extraneous matter when viewed by normal or corrected vision without magnification.

6 Limits for extractable matter

6.1 Limits for acidity or alkalinity

The pH value of the extract prepared as described in annex A shall be determined with a laboratory potentiometric pH meter using a general purpose electrode, and shall be within one pH unit of that of the control fluid.

6.2 Limits for extractable metals

An extract prepared as described in annex A shall contain not more than a combined total of 5 mg/kg of lead, tin, zinc and iron when tested by a recognized micro-analytical method, for example by an atomic absorption method. The cadmium content of the extract shall be less than 0,1 mg/kg.

7 Lubrication of syringes and needles

If the interior surface of the syringe, including the piston, and the exterior surface of the needle tube are lubricated, the lubricant shall not form pools of fluid on the interior surface of the syringe nor drops on the exterior surface of the needle tube or in the bore.

8 Range of sizes

The range of sizes of syringes and graduations shall be as given in table 1.

NOTE 2 Syringes having different nominal capacities and scale intervals are designated to encompass different presentations, but the number of types in use in a particular country could be less than those given in table 1.

Table 1 — Insulin syringes, range of sizes, graduated scale and tolerance on graduated capacity

Unit scale	Nominal capacity	Minimum length of scale	Scale interval	Tolerance on graduated capacity	
				Volumes less than half the nominal capacity	Volumes equal to or greater than half the nominal capacity
	ml	mm	units		
U-100	0,3	41	1	± (1 1/2 % of the nominal capacity + 2 % of the expelled volume)	± 5 % of the expelled volume
	0,5	43	1		
	1,0	57	1		
	1,0	57	2		
U-40	0,5	43	0,5		
	0,5	43	1		
	1,0	50	1		
	2,0	60	1		
	2,0	60	2		

9 Graduated scale

9.1 Scale

The scale shall be graduated in units of insulin and shall refer to one strength of insulin only. The nominal capacity shall be designated in millilitres (ml).

The tolerances on the graduated capacity shall be in accordance with table 1.

NOTE 3 The graduated capacity can be conveniently determined by weighing the expelled fluid. See 3.1.

The graduation lines shall be of a uniform thickness between 0,2 mm and 0,4 mm. They shall lie in planes at right angles to the axis of the barrel.

The graduation lines shall be evenly spaced along the longitudinal axis between the zero line and the line for the total graduated capacity.

When the syringe is held vertically, the ends of all graduation lines of similar length shall be vertically beneath each other.

The length of the short graduation lines shall be approximately half the length of the long lines.

The scale and scale numbers should be legible and of a colour that contrasts clearly with the syringe.

9.2 Numbering of scale

The graduation lines shall be numbered at every five units for the 0,3 ml and 0,5 ml syringes and at every 10 units for the 1,0 ml and 2,0 ml syringes.

The minimum height of the figures should be at least 3 mm.

When the syringe is held vertically with the zero line uppermost and with the scale to the front, the numbers shall appear upright on the scale and in a position such that they would be bisected by a prolongation of the graduation lines to which they relate. The numbers shall be close to, but shall not touch, the ends of the graduation lines to which they relate.

9.3 Overall length of scale

The overall length of the scale shall be in accordance with table 1.

10 Barrel

10.1 Dimensions

The barrel length shall be such that the syringe has a usable capacity of at least 10 % more than the nominal capacity or 5 mm of plunger travel beyond the scale marking, whichever is less.

10.2 Finger grips

The open end of the barrel shall be provided with finger grips which shall ensure that the syringe will not roll when it is placed with the scale uppermost on a flat surface inclined at an angle of 10° to the horizontal.

The finger grips shall be free from flash and sharp edges.

Finger grips should be of adequate size, shape and strength for the intended purpose and should enable the syringe to be held securely during use.

11 Piston/plunger assembly

11.1 General

The design of the plunger and push-button of the syringe shall be such that when the barrel is held in one hand the plunger can be depressed by the thumb of that hand. The piston shall not become detached from the plunger during the test described in annex B.

The projection of the plunger and the configuration of the push-button should be such as to enable the plunger, when in the fully inserted position, to be grasped and drawn back without difficulty

11.2 Fiducial line

There shall be a visible and defined edge serving as the fiducial line at the end of the piston for determining the graduated capacity corresponding to any syringe scale reading The fiducial line shall be in contact with the inner surface of the barrel.

For three-part syringes it is recommended that material of a dark colour be used for that part of the piston which forms the fiducial line.

11.3 Fit of piston in barrel

When the syringe is filled with water and held vertically with first one and then the other end uppermost, the plunger shall not move by reason of its own mass and the mass of the water contained. When a needle is secured to the syringe in accordance with the instructions of the manufacturer, the force required to initiate movement of the plunger to expel water from the syringe shall not exceed 15 N when measured in accordance with annex C.

The fit of the piston in the barrel should be such that the piston slides smoothly throughout the graduated length of the barrel.

12 Nozzle

12.1 Conical fitting

The male conical fitting of the syringe nozzle on syringe types 1, 2, 3 and 4 shall comply with the requirements of ISO 594-1.

12.2 Position of nozzle on end of barrel

The syringe nozzle shall be situated centrally, i e shall be co-axial with the barrel

13 Needles

Needles of syringes of types 3 4, 5, 6, 7 and 8 shall be of length not less than 12 mm and of external diameter not greater than 0,45 mm. Needles of external diameter 0,45 mm shall be in accordance with ISO 7864 Needles of external diameter less than 0,45 mm shall have the properties given in annex D, as determined by the methods given in ISO 7864.

14 Performance of assembled syringe

14.1 Dead space

When tested in accordance with annex E, the dead space shall not exceed the limits given in table 2

Table 2 — Maximum dead space

Type of syringe	Maximum dead space ml
1 and 2	0,07
3 and 4	0,10
5 and 6	0,02
7 and 8	0,01

14.2 Freedom from leakage at needle

When tested as described in annex F, there shall be no leakage of water sufficient to form a falling drop within 30 s from the unions listed in F.2.9.

When tested as described in annex G, there shall be no continued formation of air bubbles from the unions listed in G.2 6

14.3 Liquid and air leakage past piston

When tested as described in annex F, there shall be no leakage of water past the piston seal.

When tested as described in annex B, there shall be no leakage of air past the piston seal, and there shall be no fall in the manometer reading.

15 Packaging

15.1 Unit containers and self-contained syringe units

Syringes of types 1, 3, 5 and 7 shall be packed in unit containers and syringes of types 2, 4, 6 and 8 shall be packed as self-contained syringe units.

15.1.1 Unit containers (syringes of types 1, 3, 5 and 7)

The syringe, together with the needle if supplied, shall be sealed individually in a unit container.

For types 3, 5 and 7, the needle shall be supplied with a protective needle sheath.

The needle of type 3 syringes may be packaged in its own container inside the unit container.

The materials and design of the unit container should have no detrimental effects on the contents and should be such as to ensure

a) maintenance of sterility of the contents under dry, clean and adequately ventilated storage conditions;

b) minimum risk of contamination of the contents during opening and removal from the container;

c) adequate protection of the contents during normal handling, transit and storage;

d) that once opened, the container cannot be easily re-sealed, and it should be obvious that the container has been opened.

15.1.2 Self-contained syringe units (syringes of types 2, 4, 6 and 8)

The syringe shall be fitted with protective end cap.

The materials and design of the syringe unit should be such as to ensure

a) maintenance of sterility of the interior of the syringe unit, (e.g. the outside surface of the needle, the protruding part of the plunger and its push-button and the fluid path of the syringe, and needle, if fitted) under dry, clean and adequately ventilated conditions;

b) minimum risk of contamination of the contents during opening of the unit;

c) adequate protection of the contents during normal handling, transit and storage.

The syringe or the syringe unit may be provided with a means of indicating that the unit may have been opened previously.

15.2 Multiple unit pack (syringes of types 2, 4, 6 and 8)

Multiple unit packs shall contain not more than 12 syringe units of syringes of types 2, 4, 6 or 8.

The materials and design of the multiple unit pack should be such as to ensure

a) minimum risk of contamination of the syringe unit during opening of the pack;

b) adequate protection of the syringe units during normal handling, transit and storage;

c) that once opened, it should be obvious that the multiple pack has been opened.

15.3 Shelf container

A number of unit containers, syringe units, or a number of multiple unit packs shall be packed in a shelf container.

The container should protect the contents during normal handling, transit and storage.

16 Marking

If colour coding is used for indication of the insulin strength, the colour red shall be used for U-40 syringes and the colour orange shall be used for U-100 syringes.

The colours red and orange shall not be used for marking except for marking of the strength of insulin.

Colour coding, if used, can be given on the syringe, protective end caps and/or all packaging

16.1 Syringes

16.1.1 General

The barrels of syringes shall be marked with the following information:

a) appropriate graduated scale in accordance with clauses 8 and 9;

b) the text "U-40 insulin" or "U-100 insulin" whichever is applicable;

c) the word "units" or "I.U.";

d) total graduated capacity in millilitres

16.1.2 Additional marking for self-contained syringe units (syringes of types 2, 4, 6 and 8)

The syringe or unit shall additionally be marked with the following information:

a) the words "for single use" or equivalent The term "disposable" shall not be used. The ISO symbol for single use, reference ISO 7000/1051, may additionally be given (see annex J);

b) name and/or trade-mark of the manufacturer or supplier.

A warning to check the integrity of the seals of the self-contained syringe unit before use may be given

All information which appears on the barrel should be marked in such a position as to interfere as little as possible with the reading of the graduated scale

16.2 Unit containers (syringes of types 1, 3, 5 and 7)

16.2.1 The unit container shall be marked with the following information:

a) the word "sterile" or equivalent: a warning to check the integrity of the unit container before use may be given;

b) the words "for single use" or equivalent. The term "disposable" shall not be used. The ISO symbol for single use, reference ISO 7000/1051, may additionally be given (see annex J);

c) an identification reference to the batch and/or the date of manufacture;

d) the external diameter and length of the needle in millimetres, if included: the gauge size of the needle may also be marked

16.2.2 The unit container shall also be marked with the following information unless the product bears the information and is visible through the unit container:

a) identity of the contents, including the capacity of the syringe and the strength of insulin to be used;

b) name and/or registered trade-mark of the manufacturer or supplier.

16.3 Multiple unit packs (syringe types 2, 4, 6 and 8)

The multiple unit packs shall be marked with the following information:

a) the words "syringe interior sterile" or equivalent;

b) a warning to check the integrity of the seals of the self-contained syringe units before use, unless this warning is given on the syringe unit;

c) the words "for single use" or equivalent The term "disposable" shall not be used. The ISO symbol for single use, reference ISO 7000/1051, may additionally be given (see annex J)

d) name and/or trade-mark of the manufacturer or supplier unless the product bears this information and is visible through the multiple unit pack,

e) an identification reference to the batch and/or the date of manufacture,

f) the external diameter and length of the needle in millimetres, if included the gauge size of the needle may also be marked;

g) identity of the contents, including the capacity of the syringe and the strength of insulin to be used unless the information is visible through the multiple unit pack

16.4 Shelf containers

The shelf container shall be marked with the following information:

a) the word "sterile" or the words "syringe interior sterile" or equivalent as appropriate to the type of syringe contained,

b) a warning, as appropriate to the type of syringe contained, to check the integrity of the unit containers or of the seals of the self-contained syringe unit before use, unless this warning is given on the unit container or syringe unit;

c) the words "for single use" or equivalent. The term "disposable" shall not be used. The ISO symbol for single use, reference ISO 7000/1051, may additionally be given (see annex J);

d) an identification reference to the batch and date (year and month) of sterilization;

e) name and/or registered trade-mark of the manufacturer or supplier;

f) description of contents.

Annex A
(normative)

Fluid for determination of acidity/alkalinity and extractable metals

Fill 10 sterile syringes, including the needle if supplied, to the nominal capacity with freshly prepared distilled water, and maintain them at 37 °C $^{+3}_{0}$°C for 8 h. Eject the contents and combine them in a vessel made of borosilicate glass.

Prepare the control fluid by reserving an aliquot of the unused distilled water.

Annex B
(normative)

Test method for air leakage past syringe piston during aspiration

B.1 Procedure

The test shall be conducted using apparatus as illustrated in figure B.1 in accordance with the following procedure.

B.1.1 Draw into the syringe a volume of recently boiled and cooled water of not less than 25 % of the graduated capacity.

B.1.2 With the nozzle uppermost, withdraw the plunger until the fiducial line is at the maximum graduated capacity and clamp the plunger in this position as illustrated in figure B.1.

B.1.3 Connect the syringe nozzle to a reference steel female conical fitting as specified in ISO 594-1. If the needle is attached by a method other than the use of a 6 % (Luer) conical fitting, insert the needle into the rubber bung or diaphragm fitted to the female conical fitting.

B.1.4 Switch on the vacuum pump with the air bleed control open.

B.1.5 Adjust the bleed control so that a gradual increase in vacuum is obtained and a manometer reading of 88 kPa[1)] is reached.

B.1.6 Examine the syringe for evidence of air leakage past the piston.

B.1.7 Isolate the syringe and manometer assembly by means of a vacuum-tight valve.

B.1.8 Observe the manometer reading for 60 s and record any fall in reading.

B.1.9 Examine the syringe to determine if the piston becomes detached from the plunger.

B.2 Test report

The following information shall be provided:

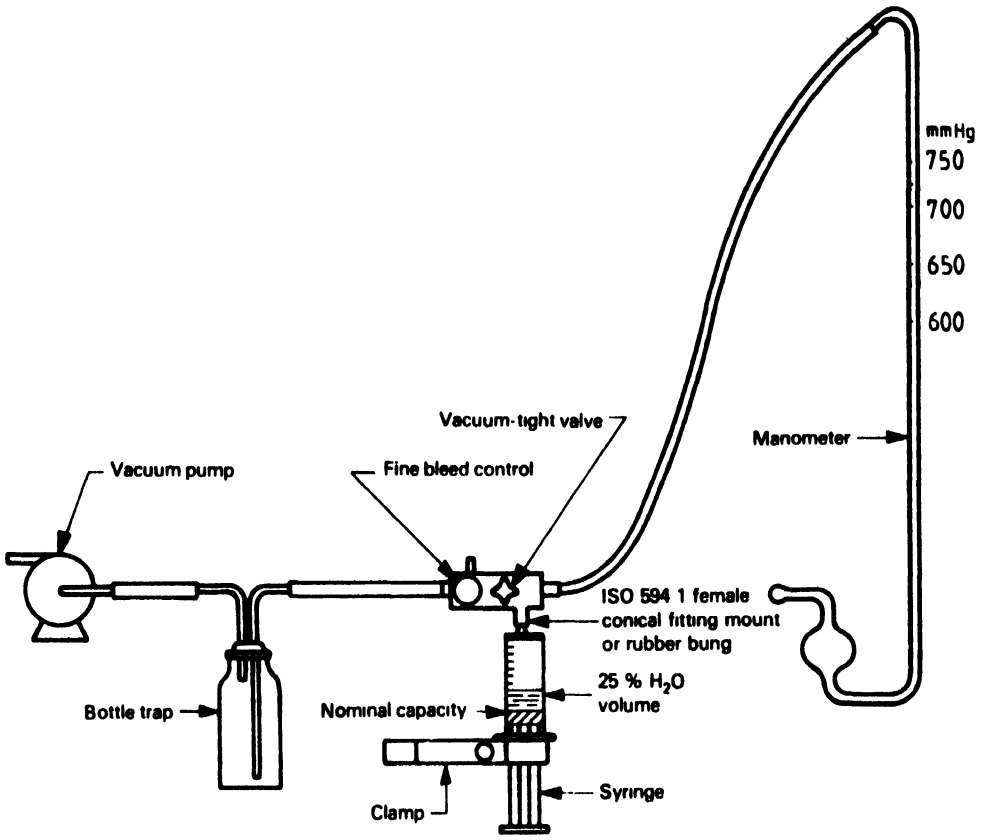
a) the identity of the syringe;

b) the date of testing;

c) a statement as to whether air leakage (as indicated in B.1.6 and B.1.8) was observed;

d) a statement as to whether the piston became detached from the plunger.

1) 1 kPa = 7,5 mmHg



NOTES

1 The apparatus can be used for all types of syringes, as the apparatus can be fitted with either a female conical fitting or a rubber bung

2 The volume of air enclosed between the syringe tip and the manometer should be as small as possible

Figure B.1 — Apparatus used in aspiration tests

Annex C
(normative)

Test method for force required to operate plunger

C.1 Procedure

C.1.1 Apply the needle onto the syringe if not fitted. Syringes of types 1 and 2 shall be fitted with a needle of external diameter of 0,40 mm.

C.1.2 Fill the syringe with water to 50 % of its indicated capacity.

C.1.3 Clamp the syringe onto a suitable test stand with the needle pointing downward.

C.1.4 Wipe away any water from the needle point.

C.1.5 Immediately apply a vertical downward force to the plunger by means of a force gauge and gradually increase the force until the plunger begins to move, the initiation of movement being indicated by the expulsion of water from the needle.

C.1.6 Maintain a force sufficient to sustain the plunger movement until it is fully depressed.

C.1.7 Record the maximum force required to operate the plunger during the test.

C.2 Test report

The following information shall be provided:

a) the identity of the syringe;

b) the date of testing;

c) the force required to initiate movement of the plunger, expressed in newtons.

Annex D
(normative)

Properties of needles with external diameter less than 0,45 mm

D.1 The diameters of needle tubes shall be in accordance with table D.1.

Table D.1 — Diameter of needle tube

Dimensions in millimetres

Nominal external diameter[1]	External diameter		Bore of needle
	min.	max.	min.
0,33	0,33	0,35	0,16
0,36	0,35	0,37	0,16
0,38	0,38	0,40	0,18
0,40	0,40	0,42	0,19

1) The nominal external diameters correspond to gauge numbers as follows: 0,33 mm (gauge 29), 0,36 mm (gauge 28), 0,38 mm (no gauge number) and 0,40 mm (gauge 27).

D.2 The stiffness of needles shall be in accordance with table D.2.

Table D.2 — Stiffness

Nominal external diameter	Span	Force	Maximum deflection
mm	mm	N	mm
0,33	9,5	1,8	0,40
0,36	9,5	2,0	0,34
0,38	9,5	2,2	0,30
0,40	9,5	2,4	0,25

D.3 The minimum strength of the bond between the hub/syringe and the needle tube shall be in accordance with table D.3.

Table D.3 — Minimum strength of bond between hub/syringe and needle tube

Nominal external diameter	Force
mm	N
0,33	22
0,36	22
0,38	22
0,40	22

D.4 The stylet diameter to test the patency of the lumen shall be in accordance with table D.4.

Table D.4 — Size of stylet to test patency of lumen

Dimensions in millimetres

Nominal external diameter	Diameter of stylet
0,33	0,11
0,36	0,11
0,38	0,11
0,40	0,12

D.5 The resistance to breakage shall be assessed in accordance with table D.5.

Table D.5 — Resistance to breakage

Dimensions in millimetres

Nominal external diameter	Distance between rigid supports and application of bending force
0,33	8
0,36	8
0,38	8
0,40	8

Annex E
(normative)

Test method for determination of dead space

E.1 Preparation of samples

E.1.1 Syringes of types 3 and 4

Remove the needle, if fitted, from the syringe and then refit it as follows.

Connect the nozzle of the syringe to the needle hub. Assemble the components by applying an axial force of 27,5 N for 5 s whilst applying a twisting action to a torque value not exceeding 0,1 N·m to give rotations not exceeding 90°.

E.1.2 Syringes of types 1, 2, 5, 6, 7 and 8

No preparation is necessary.

E.2 Procedure

E.2.1 Weigh the empty syringe including needle if appropriate, prepared in accordance with clause E.1, to the nearest 0,001 g.

E.2.2 Fill the syringe to the total graduated capacity with distilled water at 20 °C ± 3 °C, taking care to expel all air bubbles, especially from the needle if present, and, in the case of syringes without a needle, ensure that the level of the meniscus coincides with the end of the nozzle lumen.

E.2.3 Expel the water by fully depressing the plunger, and wipe dry the outer surface of the syringe.

E.2.4 Reweigh the syringe.

E.3 Calculation of results

Determine the mass of water in grams remaining in the syringe by subtracting the mass of the empty syringe from the mass of the syringe after expulsion of the water. Record this value as the dead space in millilitres, taking the density of water as 1 000 kg/m^3.

E.4 Test report

The following information shall be provided:

a) the identity of the syringe;

b) the date of testing;

c) the dead space of the syringe, expressed in millilitres.

Annex F
(normative)

Test method for liquid leakage at syringe piston and syringe nozzle/hub or needle/barrel unions during compression

F.1 Preparation of samples for testing

F.1.1 Testing for leakage past piston

Prepare samples for testing as given in F.1.1.1 to F.1.1.3.

F.1.1.1 Syringes of types 1 and 2

Connect the syringe nozzle to a reference steel female conical fitting in accordance with ISO 594-1, both components being dry. Assemble the components by applying an axial force of 27,5 N for 5 s whilst applying a twisting action to a torque value not exceeding 0,1 N·m to give rotation not exceeding 90°.

F.1.1.2 Syringes of types 3 and 4

Remove the needle, if fitted, and connect the syringe nozzle to a reference steel female conical fitting as described in F.1.1.1.

F.1.1.3 Syringes of types 5 and 6

Ensure that the union between the syringe nozzle and the needle hub is firmly assembled and does not leak.

F.1.1.4 Syringes of types 7 and 8

No preparation is necessary.

F.1.2 Testing for leakage at syringe nozzle

Prepare samples for testing as given in F.1.2.1 to F.1.2.4.

F.1.2.1 Syringes of types 1 and 2

Connect the syringe to a reference steel female conical fitting as described in F.1.1.1.

F.1.2.2 Syringes of types 3 and 4

Remove the needle, if fitted, and connect the syringe nozzle to a reference steel female conical fitting as described in F.1.1.1.

F.1.2.3 Syringes of types 5 and 6

No preparation is necessary.

F.1.2.4 Syringes of types 7 and 8

No preparation is necessary.

F.2 Procedure

F.2.1 Draw into the syringe a volume of water exceeding the graduated capacity of the syringe. If the union of the syringe nozzle and the reference steel female conical fitting, or the union of the syringe and the needle tube becomes wetted, dry the union.

F.2.2 Expel air.

F.2.3 Adjust the volume of water in the syringe to the maximum graduated capacity.

F.2.4 Seal the reference steel female conical fitting, or needle tip, as appropriate.

F.2.5 Apply a side load equivalent to a force of 0,25 N (25,5 g) to the push-button at right angles to the axis of the plunger to swing the plunger radially about the piston seal(s). Orient the plunger to permit the maximum deflection from the axial position.

F.2.6 Apply an axial force to the syringe so that a pressure is generated by the relative action of the piston and barrel of 300 kPa gauge. Maintain the pressure for 30 s.

F.2.7 Examine the syringe to detect and record any piston movement during the period of pressure application.

F.2.8 Examine the syringe for leakage of liquid past the piston seals.

F.2.9 Examine the union of the syringe nozzle and the reference steel female conical fitting or needle hub or the union of the syringe and the needle tube, as appropriate, for evidence of leakage of liquid.

F.3 Test report

The following information shall be provided:

a) the identity of the syringe;

b) the date of testing;

c) a statement as to whether leakage past the piston was observed;

d) a statement as to whether leakage, as described in F.2.9, was observed.

Annex G
(normative)

Test method for air leakage past nozzle/hub or needle/barrel unions during aspiration

G.1 Preparation of samples

Prepares samples for testing as described in clause E.1.

G.2 Procedure

G.2.1 Draw into the syringe a volume of recently boiled and cooled water of not less than 25 % of the nominal graduated capacity of the syringe. If the union of the syringe nozzle and the reference steel female conical fitting, or the union of the syringe and the needle tube becomes wetted, dry the union.

G.2.2 Expel air, except for a small residual air bubble.

G.2.3 Adjust the volume of water in the syringe to 25 % of the nominal graduated capacity.

G.2.4 Seal the reference steel female conical fitting or needle tip, as appropriate.

G.2.5 With the syringe nozzle downwards, withdraw the plunger to the total graduated capacity line. Hold for 15 s.

G.2.6 Examine the syringe for the continued formation of air bubbles from the union of the syringe nozzle and the reference steel female conical fitting or needle hub, or from the union of the syringe and the needle tube, as appropriate.

Discount bubbles that appear during the first 5 s.

G.3 Test report

The following information shall be provided:

a) the identity of the syringe;

b) the date of testing;

c) a statement as to whether leakage, as described in G.2.6, was observed.

Annex H
(informative)

Preparation of extract for test for pyrogenicity and toxicity

Using sterile reagents and apparatus, and aseptic technique, fill at leat three sterile syringes, including the needle, if supplied, to the nominal capacity with pyrogen-free saline solution containing 9 g/l of sodium chloride of recognized analytical quality in freshly prepared distilled water, and maintain them at 37 °C $^{+3}_{0}$ °C for 8 h. Eject the contents and combine them in a vessel made of borosilicate glass

Annex J
(informative)

Symbol for "do not re-use"

J.1 General

The symbol to denote equipment intended for single use is ISO symbol registration number 7000/1051, as published in ISO 7000:1989, *Graphical symbols for use on equipment — Index and synopsis*. Further information on design, dimensions and application of ISO symbols is given in ISO 3461:1987, *General principles for the creation of graphical symbols — Part 2: Graphical symbols for use in technical product documentation*.

J.2 Original design

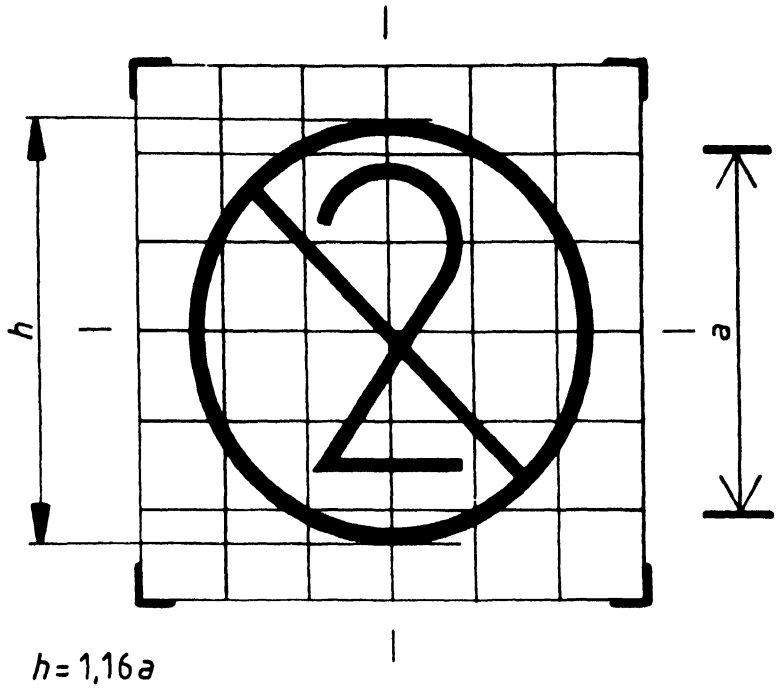
Symbol ISO 7000/1051 is shown in figure J.1. The four visual centring lines are an aid for positioning the symbol and for relating it to its surroundings, but do not form part of the symbol.

The thickness of the lines is 2 mm. Dimension *a* is the nominal size of the original design of all ISO symbols and is normally made equal to 50 mm. In many cases, including ISO 7000/1051, the actual dimension differs slightly, and the outside diameter of the circle (dimension *h*) of the original design is 1,16*a*, i.e. 58 mm.

No colour is specified for ISO 7000/1051.

J.3 Reduction and enlargement of original design

For symbol application, it may be necessary to reduce or enlarge the size of the original to a suitable size at which it will actually appear. The nominal dimension *a* should be used as a gauge. Practice has shown that dimension *a* may be reduced to 3 mm without the symbol losing its legibility. However, symbol legibility when reduced in size should be checked.



$h = 1{,}16\,a$

NOTE – The visual centring lines do not form part of the symbol.

Figure J.1 — ISO symbol for single use, number ISO 7000/1051

AMENDMENT 1

Page 1

Clause 2 Normative references

Add "ISO 9626, *Stainless steel needle tubing for manufacture of medical devices*"

Definition 3.1

Change "gratuated" to "graduated"

Page 5

Clause 13 Needles

Change the title to "**Needle tubing and needles**" Delete the entire text, and substitute the following new text

13.1 Needles for syringes of types 3 and 4

Needles for syringes of types 3 and 4 shall be in accordance with ISO 7864, except for the dimensions and test parameters which shall be in accordance with annex D of this International Standard

13.2 Needle tubing for syringes of types 5, 6, 7 and 8

Needle tubing for syringes of types 5, 6, 7 and 8 shall be in accordance with ISO 9626, except for the dimensions and test parameters which shall be in accordance with annex D of this International Standard The needle point shall be in accordance with ISO 7864

NOTE ISO 9626 1991 is at present undergoing amendment, the values in annex D (see below) are taken from the most recent draft. Some values therefore differ from those given in ISO 7864 1993 and ISO 9626 1991 When the ISO 9626 amendment is published, clause 13 and annex D of this International Standard may be replaced by a normative cross-reference to ISO 7864 and amended ISO 9626

Page 12

Annex D

Delete the entire annex D and substitute the following.

Annex D
(normative)

Properties of needles and needle tubing

D.1 The diameters of the needle tubing shall be in accordance with Table D.1.

Table D.1 — Diameters of needle tubing

Dimensions in millimetres

Nominal outside diameter [a]	Outside diameter		Minimum inside diameter
	min.	max.	
0,25	0,254	0,267	0,114
0,30	0,298	0,320	0,133
0,33	0,324	0,351	0,133
0,36	0,349	0,370	0,133
0,40	0,400	0,420	0,184
0,45	0,440	0,470	0,232

[a] The nominal outside diameters correspond to gauge numbers as follows: 0,25 mm (gauge 31), 0,30 mm (gauge 30), 0,33 mm (gauge 29), 0,36 mm (gauge 28), 0,40 mm (gauge 27) and 0,45 mm (gauge 26).

D.2 The stiffness of the needle tubing shall be in accordance with Table D.2 when tested as described in ISO 9626.

Table D.2 — Stiffness

Nominal outside diameter	Span mm ± 0,1	Force N ± 0,1	Maximum deflection mm
0,25	3,5	5,5	0,35
0,30	5,0	5,5	0,40
0,33	5,0	5,5	0,32
0,36	5,0	5,5	0,25
0,40	9,5	5,5	0,60
0,45	10,0	6,0	0,56

D.3 The minimum strength of the bond between the hub/syringe and the needle tubing shall be 22 N when tested in accordance with ISO 7864.

D.4 The stylet diameter to test the patency of the lumen as described in ISO 7864 shall be in accordance with Table D.3.

Table D.3 — Size of stylet to test patency of lumen

Dimensions in millimetres

Nominal outside diameter	Diameter of stylet $^{0}_{-0,01}$
0,25	0,08
0,30	0,11
0,33	0,11
0,36	0,11
0,40	0,15
0,45	0,18

D.5 The resistance to breakage shall be assessed in accordance with Table D.4 when tested as described in ISO 9626.

Table D.4 — Resistance to breakage

Dimensions in millimetres

Nominal outside diameter	Distance between rigid supports and application of bending force ± 0,1
0,25	8
0,30	8
0,33	8
0,36	8
0,40	8
0,45	10

(*Continued from second cover*)

This standard describes syringes with or without needles for use with 40 units of insulin/ml (U-40) and 100 units of insulin/ml (U-100) It is recommended that syringes graduated for only one strength of insulin be used to avoid accidents For using more than one strength of insulin, the importance of having individual syringes appropriately graduated for only one strength of insulin as specified in this standard is emphasized Serious problems may result if a syringe is used with a strength of insulin for which it is not designed. If the syringe is used for mixing different types of insulin, it is strongly recommended that the procedure is performed in the same order each time

Annexes A, B, C, D, E, F and G form an integral part of this standard Annexes H and J are for information only

The text of standard has been approved as suitable for publication as Indian Standard without deviations Certain conventions are, however, not identical to those used in Indian Standards Attention is particularly drawn to the following

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard', and

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point ( ) as the decimal marker

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist The corresponding Indian Standards which are to be substituted in their place are listed below along with their degree of equivalence for the editions indicated

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 594-1 1986	IS 3234 (Part 1) 1986 Conical fittings with a 6 percent (Luer) taper for syringes, needles and other medical equipment Part 1 General requirements (*second revision*)	Identical
ISO 7864 1993	IS 10654 2002 Sterile hypodermic needles for single use (*third revision*)	do

The technical committee responsible for the preparation of this standard has reviewed the provisions of ISO 9626, referred in this adopted standard and has decided that it is acceptable for use in conjunction with this standard

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS 2 1960 Rules for rounding off numerical values (*revised*)' The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard

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